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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/868,098	06/14/2001	Beate Diefenbach	MERCK 2251	5446

23599 7590 07/28/2005

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EXAMINER

ROY, GARGI

ART UNIT PAPER NUMBER

1653

DATE MAILED: 07/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/868,098

Applicant(s)

DIEFENBACH ET AL.

Examiner

Gargi Roy

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1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-16 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-12, drawn to viral peptide sequences coding ligands of integrin $\alpha_v\beta_6$ and the medicament and pharmaceutical preparation thereof, and making a medicament thereof, (claims 11-12), classified in class 530, subclass 300.
- II. Claims 13-14, drawn to recombinant virus DNA sequences encoding ligands of integrin $\alpha_v\beta_6$, classified in class 536, subclass 23.5.
- III. Claims 15-16, drawn to virus containing the coat protein corresponding to the sequences of the ligands of integrin $\alpha_v\beta_6$ peptides and using the virus for the production of the medicament (claim 16), classified in class 435, subclass 320.1.

The inventions are distinct, each from the other because of the following reasons:

The peptides of Invention I are related to the nucleic acids of Invention II, by virtue of encoding same. The DNA molecule has utility for the recombinant production of the protein in a host cell. Although the DNA molecule and protein are related since the DNA encodes the specifically claimed protein, they are distinct inventions because the protein product can be made by another and materially different process, such as by synthetic peptide synthesis or purification from the natural source. Further, the DNA

may be used for processes other than the production of the protein, such as nucleic acid hybridization assay.

The virus of Invention III and the peptides of Invention I are related, by virtue of being the host for the production of ligands of integrin $\alpha_v\beta_6$. Although, the virus is engineered to produce the ligands of integrin $\alpha_v\beta_6$, it is not just limited to this function. The virus and the peptide sequences are structurally and functionally distinct entities and therefore these inventions are patentably distinct.

The nucleotide sequence of Invention II is related to virus of Invention III, by virtue of being engineered to produce ligands of integrin $\alpha_v\beta_6$. However, the nucleic acid itself is distinctly different from virus and both are wholly different compounds having different structure and functions. Therefore, these Inventions are distinct.

Upon election of an Invention, Applicants must also elect a single sequence for search. This is NOT a species election. For example, the formula at Claim 1 is drawn to 148 million sequences. The formula is also a non-conserved sequence as noted by non-conservative amino acid substitutions. These sequences, therefore, differ in structure and function. Applicants must elect a single sequence for examination because the formula of SEQ ID NO.2 does not reflect a single or related polypeptide sequence. This elected sequence must be in computer readable form (CRF) for search.

If Applicants insist that all sequences be examined, Applicants must provide a single sequence to represent all sequences for search. It will be understood that if prior

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art is found on that sequence then all sequences claimed will be considered to be obvious variants of that sequence and rejected accordingly.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

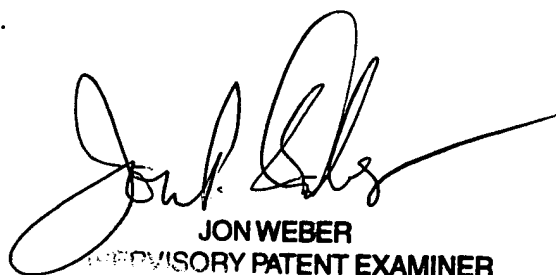
Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gargi Roy whose telephone number is 571-272-1306. The examiner can normally be reached on 8:30 am-5:00pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



JON WEBER
ADVISORY PATENT EXAMINER